Otto Bock
HEALTH CARE

1022924

OCT 17 2002

A COMPANY OF THE
OTTO BOCK GROUP

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

North American Headquarters
Two Carlson Parkway N., Suite 100
Minneapolis, MN 55447-4467
Phone 763-553-9464
Toll-free 1-800-328-4058
Fax 763-519-6153
Toll-free Fax 1-800-962-2549
www.ottobockus.com

A. General Information

1.	*Submitter's Name:*	Otto Bock Health Care, Inc.
2.	*Address:*	Two Carlson Parkway N., Suite 100 Minneapolis, MN 55447-4467
3.	*Telephone:*	763-553-9464
4.	*Contact Person:*	E.P. (Bert) Harman
5.	*Date Prepared:*	August 14, 2002
6.	*Registration Number:*	2182293

Technical Center
14800 28th Avenue North, Suite 110
Minneapolis, MN 55447-4873
Phone 763-519-9000
Toll-free 1-800-795-8846
Fax 763-519-6151
Toll-free Fax 1-800-810-7994
www.ottobockus.com/services

B. Device

1.	*Name:*	Sherpa Mobility System (Manual Wheelchair)
2.	*Trade Name:*	Sherpa Mobility System (Manual Wheelchair)
3.	*Common Name:*	Manual Wheelchair
4.	*Classification Name:*	Manual Wheelchair
5.	*Product Code:*	IOR
6.	*Class:*	I
7.	*Regulation Number:*	890.3850

Customer Support &
Distribution Center
14630 28th Avenue North
Minneapolis, MN 55447-4821
Phone 763-553-9464
Toll-free 1-800-328-4058
Fax 763-519-6150
Toll-free Fax 1-800-962-2549

Design & Manufacturing Center
3820 Great Lakes Drive
Salt Lake City, UT 84120-7205
Phone 801-956-2400
Fax 801-956-2401

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Otto Bock Healthcare
E. P. (Bert) Harman
CEO/President
2 Carlson Parkway, North
Suite 100
Minneapolis, Minnesota 55447-4467

Re: K022924
Trade/Device Name: Sherpa Mobility System (Manual Wheelchair)
Regulation Number: 890.3850
Regulation Name: Wheelchair, mechanical
Regulatory Class: Class I
Product Code: IOR
Dated: August 14, 2002
Received: September 4, 2002

Dear Mr. Harman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: *To be determined*

Device Name: Sherpa Mobility System (Manual Wheelchair)

Indications for Use:

- Manual transportation device for person who are unable to walk or have a walking impediment, propulsion by an attendant.

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR OVER-THE-COUNTER USE ✓
(optional Form 1-2-96)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022924